ACTIVITY REPORT 2022

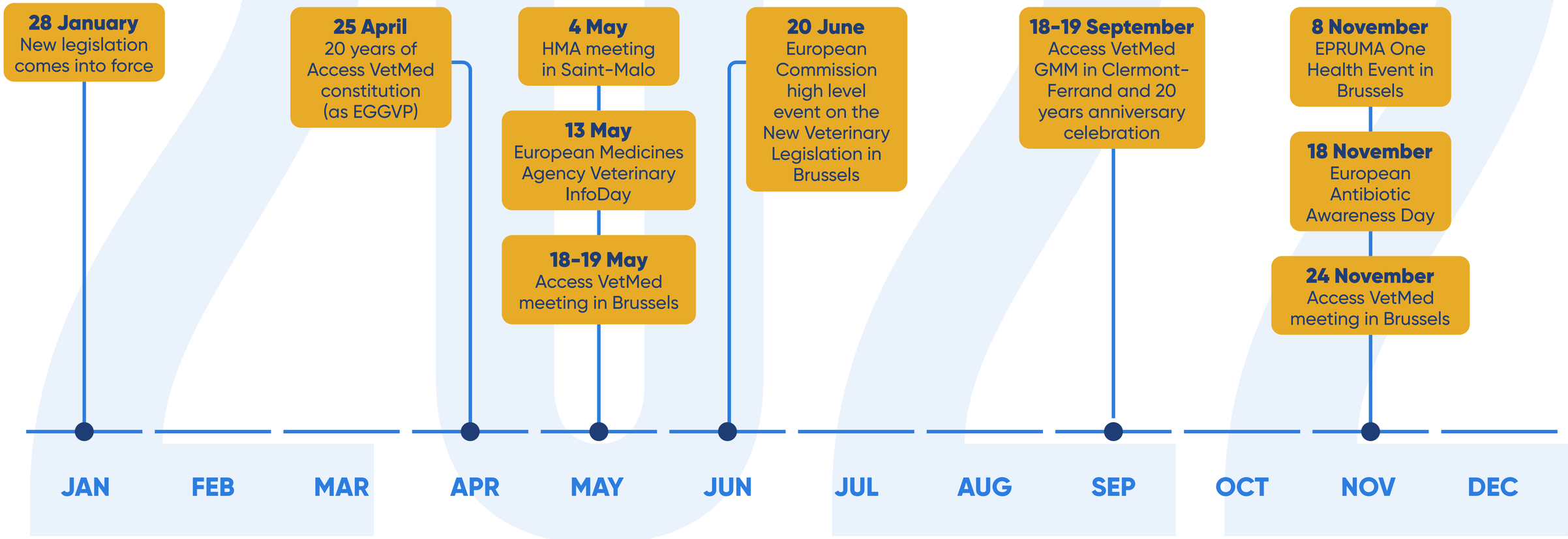
Access VETMED

Committed to animal well-being in Europe

Striving to increase the Access - Availability, Compliance, Convenience, Efficacy, Safety, and Savings - of Veterinary Medicines to veterinarians and farm and companion animal owners in Europe.

accessvetmed.eu

TIMELINE


28 January
New legislation comes into force
25 April
20 years of Access VetMed constitution (as EGGVP)
4 May
HMA meeting in Saint-Malo
13 May
European Medicines Agency Veterinary InfoDay
18-19 May
Access VetMed meeting in Brussels
20 June
European Commission high level event on the New Veterinary Legislation in Brussels
18-19 September
Access VetMed GMM in Clermont-Ferrand and 20 years anniversary celebration
8 November
EPRUMA One Health Event in Brussels
18 November
European Antibiotic Awareness Day
24 November
Access VetMed meeting in Brussels
JAN
FEB
MAR
APR
MAY
JUN
JUL
AUG
SEP
OCT
NOV
DEC

FROM THE CHAIR

Dolores Cainzos

Leo Aerden, Treasurer / Andreas Werner, Board Member / Dolores Cainzos, Chair / Slavka Pavlič, Secretary / Xavier Molins, Vice Chair

In 2022 our association held its 20th anniversary. Access VetMed was founded in 2002 as the European Group for Generic Veterinary Products, EGGVP. At that point of time, the first generic medicines for animals had entered the market. A group of companies gathered to bring out the voice of the generic industry. They wanted to assure that the new veterinary legislation was interpreted in line with its intentions to create balanced competition and allow the access to medicines.

In two decades we have grown from the original 14 to 26 members active in all EU member states. Access VetMed has become a platform for collaboration and knowledge sharing amongst its members. It has defended the interests of the generic producers, many of which have also developed added value products with enhanced features. The common objective has been to secure availability of the veterinary medicines in Europe, also in smaller markets, and bring savings to the farmers and other animal owners.

Together, we have become a recognised animal health stakeholder in the EU as we have worked to bring our members' views to the EU decision makers and authorities. This is what we will continue to do in the future as well. We want to make sure our members, including small and medium-sized companies, continue to be heard, understood, and taken into account when rules and regulations that impact them, are being prepared and implemented. This is how we can increase the access to veterinary medicines for the benefit of the farm and companion animal owners, and eventually for the benefit of the animals.

Ahead of its 20th anniversary year, the European Group for Generic Veterinary Products, EGGVP, renewed its name and became Access VetMed. With this, we also wanted to acknowledge that our members increasingly produce added-value veterinary products that contain improved features, such as a more convenient form, dosage or palatability compared to the originator. This also brings more access to treatments.

Our 20 years anniversary was marked by our general managers' meeting, gathering over 60 participants in Clermont-Ferrand, France. In addition to the official annual meeting, we looked back and celebrated our successes in voicing the interests of the generic and added value veterinary medicines and of the small and medium-sized companies. It was also a perfect moment to vision and discuss the future challenges for the association and the sector, including EU policies.

We are thankful to all our members for their dedication and cooperation during these two decades, and making our voice heard. Together, we will continue our mission to increase access to veterinary medicines for the veterinarians, and farm and companion animals in Europe.

FROM THE TECHNICAL DIRECTOR

Elsa Vecino

After twelve years of legislative work, the new veterinary medicine legislation became applicable in January 2022. It has been a year of considerable effort to adapt to the new regulation, due to the high resources needed and to the many difficulties that have arisen.

The big goal of the legislators was to ease administrative burden both for the industry and the authorities, as well as to increase the availability of medicines for all animal species and in all the EU geographies. These key benefits of the regulation were not yet experienced during 2022, but bigger and smaller companies in Access VetMed will continue working together, and side by side with regulators, towards such common goals.

Geopolitical factors did not make things easier for our members either. The Ukraine crisis has directly affected global energy and commodity prices on the pharmaceutical supply chain, which has seen high increases in production costs.

On the positive side, I would highlight the joint effort to get the European Parliament reject a motion to restrict the scope of antibiotic use for animals. Stakeholders and MEPs listened to our plea to support to the EU's One Health approach and to trust in the scientific advice in addressing the challenge of antimicrobial resistance. It was very gratifying seeing MEPs support to veterinarians so that they can retain access to specific life-saving treatments for both farm and companion animals.

But the most rewarding in 2022 was the physical gathering with our associate members again, finally after 3 years due to the COVID-19 pandemic. It was great seeing many familiar and also new faces, and the lively exchange of views and knowledge. We will continue to work hard to accompany our members though the regulatory adaptations as well as to make sure that the voice of the generic and added-value veterinary medicines is heard across Europe. I want to end with a note of thanks to our peers, EU stakeholder organisations and authorities, with a special note of gratitude to the EMA Veterinary Division team for the great training and information provided to our members on the new regulation, and also to the CMDv for their continued efforts and collaboration with the aim to have a better understanding of each other's' concerns and commonly work for a smoother implementation of the legislation.

WORKING GROUPS HIGHLIGHTS

Our working groups:

- → Antimicrobials and antimicrobial resistance
- → Regulatory procedures
- → Variations
- → Quality
- → Telematics
- → Pharmacovigilance
- → Ecotoxicity and ERA
- → Safety and efficacy
- → Labelling and packaging
- → Immunological VMPs
- → Bioequivalence

Xavier Molins

for Quality Working Group

2022 was quite an intense year within the Quality Working Group at Access VetMed, as aside from various matters associated to the introduction of Animal Health Regulation 2019/6, we had to deal with three main 'hot' topics:

First of all, the follow up on EMA's feedback to the request from the European Commission to evaluate the impact of the removal of Titanium dioxide from the list of authorised food additives on medicinal products. In that respect, the potential actions and consequences to our Members was well covered as part of the Technical meetings held in Brussels, and we also took active part in meetings with stakeholders from other industry sectors affected by the same removal in order to prepare and send a consolidated/ harmonised response to the EMA.

Also linked with future 'prohibitions', the Group had to closely monitor the future ban of PFAS (per- and polyfluorinated substances) due to the impact to our industry and concerns to some active ingredients. AVM completed a "Call for evidence" document that was submitted to ECHA, and we are glad to announce that based on documents like this, and the lobbying conducted by the whole animal and human pharmaceutical industry, active ingredients will finally be out of the scope of the ban. Having said that, the ban may still affect other materials indirectly used in the manufacture of VMPs (e.g. filters, stoppers, primary containers, ...). Therefore, we will continue to monitor the evolution of this development.

Not less important, we submitted comments in relation to the EMA Concept paper covering the revision of Annex 4 of the GMP guidelines for the manufacture of VMPs and we started to closely monitor the new GMP Annex I (Manufacture of sterile medicinal products) that may have important consequences and added burden to most of our Members. In that instance, we are in the process of organising an internal training session/webinar during 2023 in order to assist/facilitate the adoption of this new Annex I.

In addition to the above, the Quality WG also participated at EMA's QWP/ Interested Parties Meeting on May 2022, and also provided comments to EMA on the revision 2 of VICH GL18(R2) (Impurities: residual solvents in new VMPs, active substances and excipients) and to the Concept paper on the need for amendment of the guideline on Quality Aspects of Pharmaceutical Veterinary Medicines for administration via drinking water (Annex on the concomitant use of Veterinary Medicinal Products and biocides). From what concerns to the later topic, EMA recently issued the final guideline for consultation, and this is under deep review by the members of the Quality WG.

Andreas Werner

for Pharmacovigilance Working Group

The new legislation becoming effective in January 2022 has brought many changes in pharmacovigilance activities, but the chair of the working group, Andreas Werner from Bela-Pharm, sees light at the end of the tunnel. “The companies are getting used to the new pharmacovigilance activities, partly thanks to EMA’s training. However, constant changes to the databases – which are appreciated as they provide new functionalities - require constant adaptation in our processes. The year 2023 will still be a year of transition until the databases and the procedures are established in such a way that we can confidently say that we are meeting the legal obligations”.

Sonja Schwab

for new IT Pharmacovigilance systems

With the implementation of regulation 2019/6 we had to adapt our PhV processes to a set of new databases (EVVET/DWH/IRIS). Understanding how to identify new reports in EVWEB, how to ask the right questions in data ware house as well as how to interpret the results, and how to ensure that signals and annual statements are submitted for all relevant products has been a major challenge for marketing authorization holders.

Jaka Petrič

for Telematics Working Group and UPD

The new data registry, the union product database (UPD) has been one of the big efforts for all, EMA, national agencies and companies to set up. The adaptation is still ongoing and, although EMA and national agencies are putting a lot of effort, all the products expected to be in UPD are not uploaded yet and certain features are still missing. The existing products data is lacking quality. Companies are using a lot of time to check and communicate with national agencies to enhance it so that they could submit the necessary information, for example variations not requiring assessment, sales volumes and availabilities.

Pablo Tejero

for ERA Working Group

As our industry has seen an increased administrative burden, luckily in the area of environmental risk assessment (ERA) the requirements for generics were rationalized. Pablo Tejero from Labiana, and chair of the ERA working group, reports that generic MAHs are no longer required to duplicate the assessments for same ecotoxicity scenarios of products, which is a welcome change.

Inma Zorrilla

for Regulatory Procedures Working Group

The new legislation and associated procedures have brought us companies and authorities closer together and helped understand each other's perspective. Some processes have changed completely, such as submitting variations, and this has been somewhat challenging. We have given feedback to the authorities to help them update and align guidelines and processes as we go along. Even though we are not quite there yet with the desired outcome of improved efficiency and reduction of administrative burden, our members give credit to the authorities for trying to solve the issues and for keeping an ongoing and open dialogue with the industry.

Špela Miklič

for Bioequivalence WG

Our group was very busy in 2022 preparing comments and opinion on the a new VICH project / guideline related to In vitro Dissolution for Immediate Release Solid Oral Veterinary Dosage Forms (incorporating biowaivers with bioequivalence established on one strength). Exchanges with international stakeholders took place on this topic so as to bring the views of the EU generic industry into consideration.

2022 FIGURES

8.2K

8.200 direct jobs in Europe, supporting local economics, employment and welfare

31

Active in 31 European countries, including smaller markets

2.2B

Turnover 2.2 Billion euro

26

Generic and added value veterinary medicines companies

45%

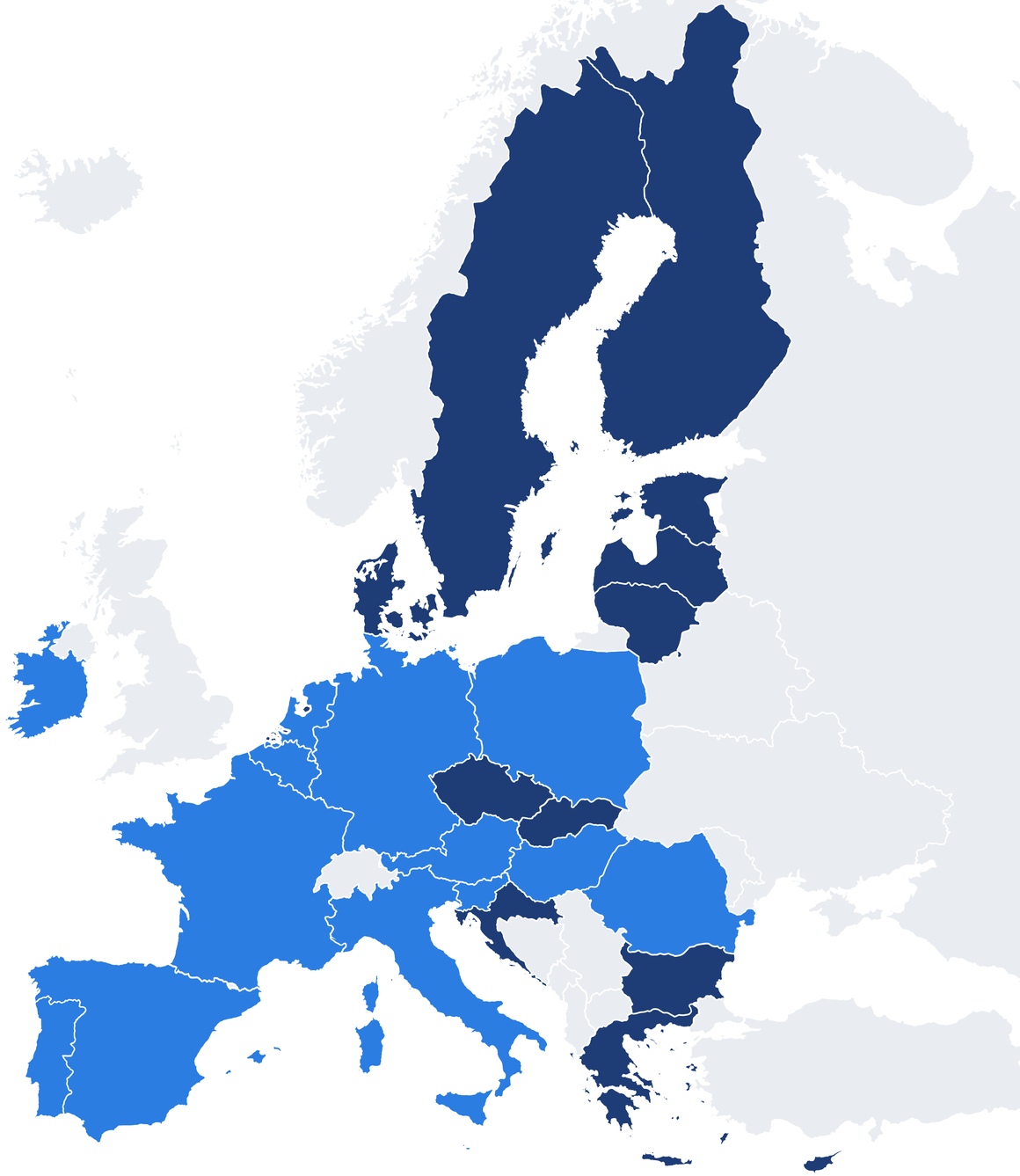
Hold of all the generic veterinary medicines marketing authorisations in Europe

36

Offering products for 36 different species, including minor species and most therapeutic groups and animals

MEMBERS

Alfasan NEDERLAND
ALPHAVET
andrés pintaluba
SERVICE AniMeD TIERARZNEIMITTEL
beaphar Because pets are family too
bela-pharm
Bimeda Excellence in Animal Health
CALIER
chanelle PHARMA
chemifarma S.p.A.
Dechra Pharmaceuticals PLC
DP DÔMES PHARMA
dox-a
InoVet
KARIZOO AN ALIVIRA GROUP COMPANY
kela focus on health
KRKA
LABIANA
MAYMO
LIVISTO
FARMAVET GROUP
s.p. veterinaria
vetAgro
VetViva Richter
WDT The Veterinary Company.
ZOOPAN SAÚDE E NUTRIÇÃO ANIMAL



Our vision is to achieve a transparent and competitive regulatory and business environment where all stakeholders have equal share of voice and play an active role in protecting animal health and welfare, human safety, and the environment.

Access
VETMED

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